TRANSPARENCY OF ARTIFICIAL INTELLIGENCE / MACHINE LEARNING (AI/ML)-ENABLED MEDICAL DEVICES: FDA VIRTUAL PUBLIC WORKSHOP

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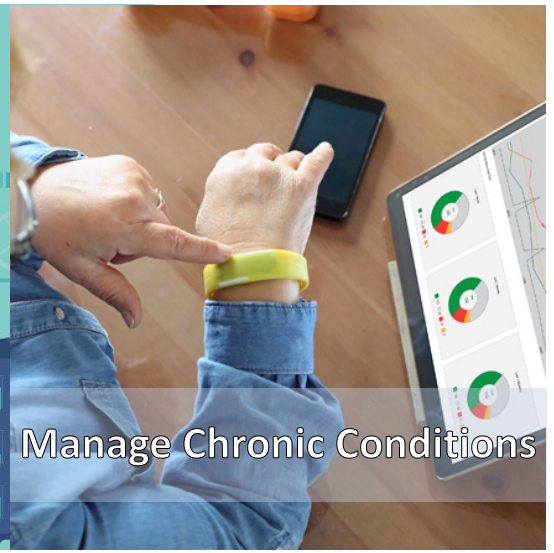
www.fda.gov/digitalhealth

Advances in AI/ML

rming Health Systems and Daily Lives



Some of the greatest benefits are AI/ML's ability to learn from real-world use and experience, and its capability to improve its performance.

Unique Considerations

We recognize the need for careful oversight to ensure the benefits of these advanced technologies outweigh the risks to patients.

- Usability
- Trust
- Equity
- Accountability

Proposing a Regulatory Framework

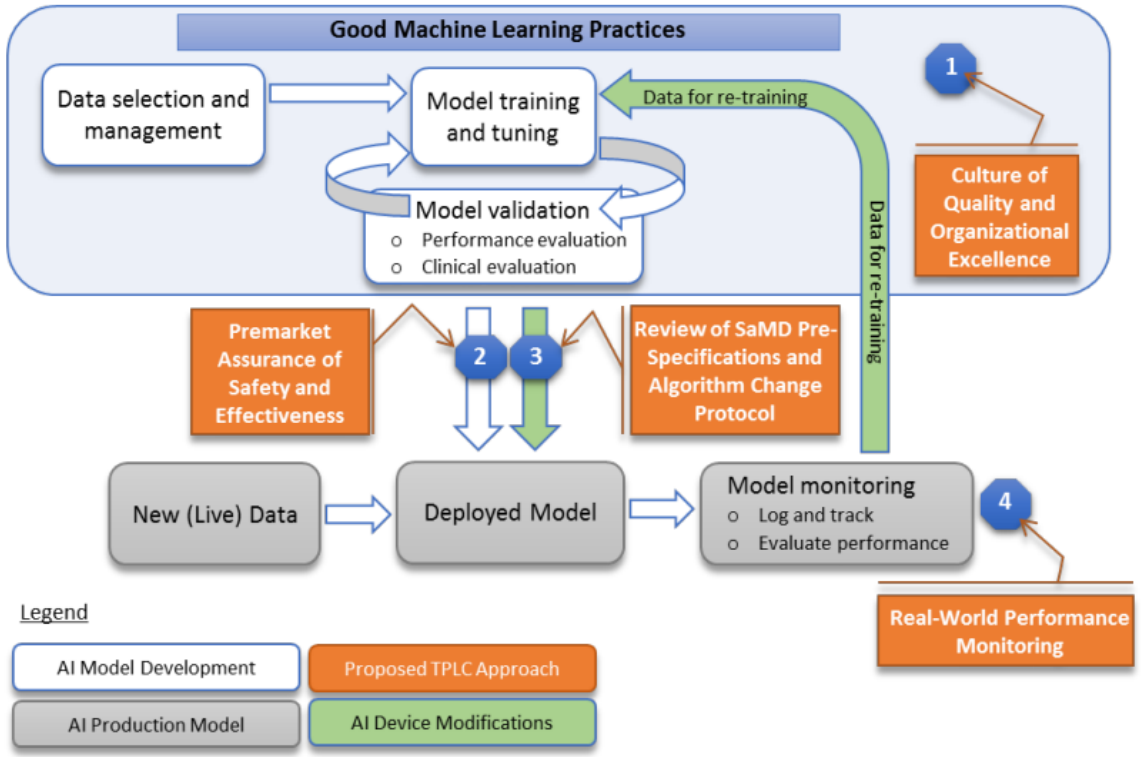


Figure 2: Overlay of FDA's TPLC approach on AI/ML workflow

Published in 2019

Discussion Paper and Request for Feedback

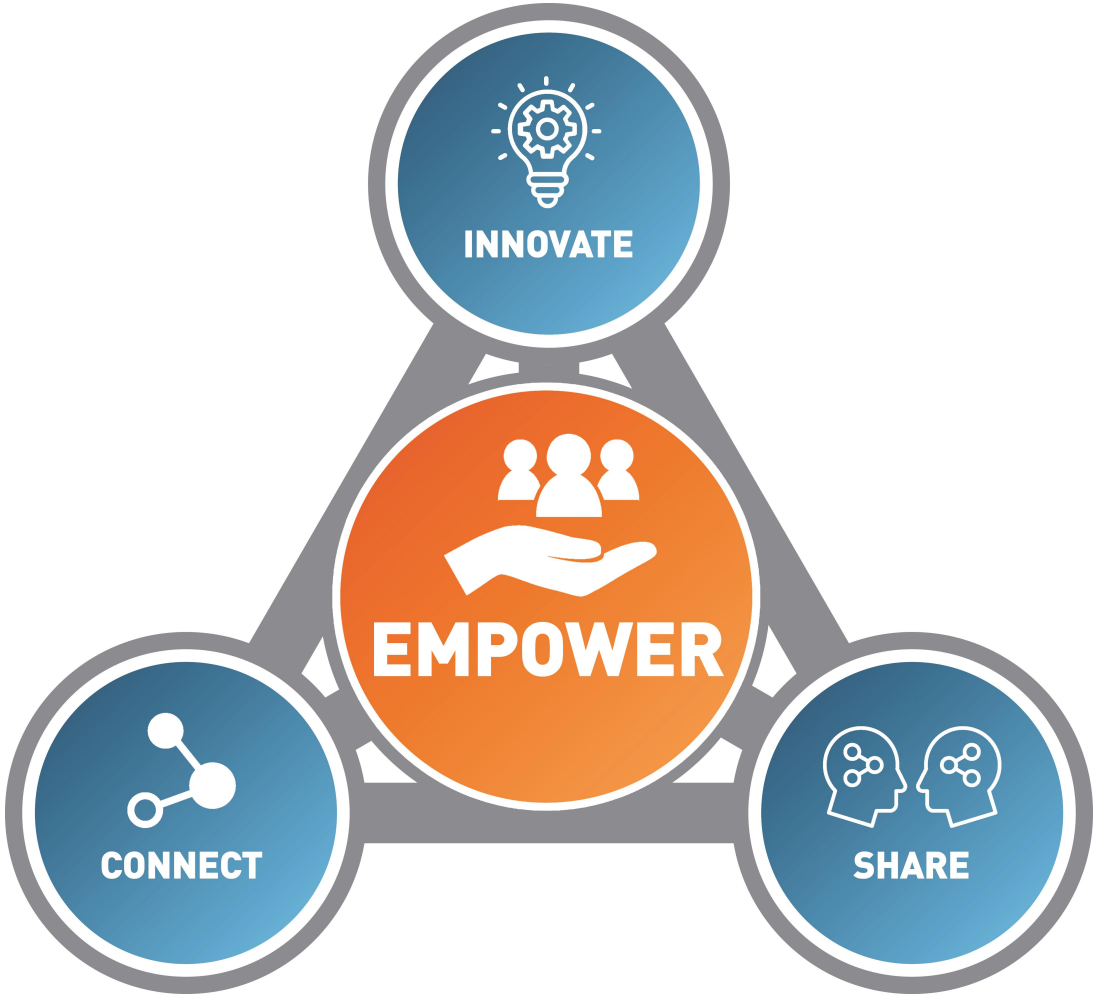
- Received stakeholder feedback through:
  - > 1,000 comments on public docket
  - > 30 publications in peer-reviewed journals
  - Pre-submission meetings on AI/ML devices
  - Patient Engagement Advisory Committee Meeting

Partnering to Foster Responsible Innovation

Launched in 2020

FDA's Digital Health Center of Excellence

- Part of the planned evolution of the digital health program
- Aligning strategy with implementation
- Driving synergy for digital health efforts
- Preparing FDA for the digital health future



Next Steps: Tailoring a Regulatory Framework

Published in 2021

Action Plan for AI/ML-Based SaMD

Outlines five next steps to advancing access:

1. Update the proposed AI/ML regulatory framework
2. Strengthen FDA's role in harmonizing GMLP
3. Foster a patient-centered approach
4. Support development of regulatory science methods
5. Advance real-world performance pilots

Understanding Transparency

Source: [The Medical Futurist]

Transparency is crucial to help providers and patients make informed decisions about their use of a device with AI/ML capabilities.

Transparency for All Users

Common User Questions:

- *How does it work?*
- *How does it influence care?*
- *Will it work for my patient in a particular environment?*
- *What is being done with my data?*
- *What do I need to know?*
- *What are the benefits? Risks? Limitations?*

Collaborating with You

Our Goal is to Hear from You!

- Establishing safety and effectiveness
- Considerations for achieving transparency for users
- Lessons learned in the real world
- Possible means of promoting transparency

Please submit your comments regarding the workshop to www.regulations.gov Docket No. FDA-2019-N-1185 by November 15, 2021.